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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,486	06/18/2007	Michael D. Dake	13720-105068US2	1914
65989	7590	05/07/2010		
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			05/07/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,486	<b>Applicant(s)</b> DAKE ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-191 is/are pending in the application.
- 4a) Of the above claim(s) 1-66 and 75-191 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence non-compliance notice</u> .   |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :06/20/07; 01/17/08; 01/24/08; 03/21/08; 10/07/08; 03/05/09; 07/06/09; 07/27/09.

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### **DETAILED ACTION**

Applicant's election without traverse of Group III, claims 67-74, to the species (gly)<sub>p</sub>-RKKRRQRRR-(gly)<sub>q</sub> where p is 0 and q is 1, in the reply filed on January 25, 2010, is acknowledged.

Claims 1-66, 75-191 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 67-74, to the species (gly)<sub>p</sub>-RKKRRQRRR-(gly)<sub>q</sub> where p is 0 and q is 1, is currently under examination.

Priority: The request for priority to provisional application 60/550,014, filed March 3, 2004, is acknowledged.

#### ***Failure to Comply with the Sequence Rules***

Where the description of a patent application discusses a sequence of 4 or more amino acids, reference must be made to the sequence by use of the sequence identifier preceded by "SEQ ID NO:" in the text of the description even if the sequence is also embedded in the text of the description of the patent application (see 37 CFR 1.821, especially paragraphs (a)-(d)). The sequence identifier may be used in either the drawing or the Brief Description of Drawings (see MPEP 2422).

#### ***Objection to the Specification:***

The specification is objected to for failure to comply with the sequence rules for the reasons as given above. The specification refers to sequences without identifiers at page 17,

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[0066], page 19 [0069-0070], p. 28 [0093], p. 45 [0142], p. 47 [0149], p. 50 [0157], p. 53 [0166], p. 55 [0172], p. 59 [0180, 0183], p. 61 [0188], p. 64 [0200]. Appropriate correction is required.

### ***Claim Objections***

Claims 67, 70 are objected to because of the following informalities:

claim 67, line 2 recites "the protein". It is suggested the "the protein" be amended to recite "the biologically active protein" since "a biologically active protein" is recited in line 1 of claim 67.

claim 70 recites "VEGF." The term "VEGF" should be spelled out in full the first time it is recited in the claims.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 recites the limitation "the association" in the claim. There is insufficient antecedent basis for this limitation in the claim. Additionally, claim 67 recites the association between the carrier and the biologically active protein is non-covalent. It is unclear if the carrier and the biologically active protein are being administered together as one mixture onto the same

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topical region or if said carrier and said biologically active protein are two separate compositions that are administered separately onto two different topical regions. Further clarification is requested.

Claim 68 recites the limitation "the composition" and "the agent" in the claim. There is insufficient antecedent basis for this limitation in the claim and its parent claim. Further, claim 68 is improperly dependent on claim 66 (which is a claim drawn to a kit and has currently been withdrawn by the Examiner because it is drawn to a non-elected invention).

Since claim 68 has improper dependency, claims 69-74 are also improperly dependent claims because they are dependent on claim 68. Appropriate correction is required.

Claims 70-74 recite the limitation "the therapeutic protein" in the claims. There is insufficient antecedent basis for this limitation in the claims and their parent claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Ilum (US 5744166; IDS 03.05.09). For examination purposes, the instant claims have been interpreted as: a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a

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biologically active protein, wherein the carrier and the biologically active protein associate non-covalently.

Illum teaches a composition comprising a polycationic polymer, i.e. polylysine, and a pharmaceutically active agent, wherein the carrier is suitable for topical administration (col. 11 lines 30-47, col. 12 line 31). The composition comprising the polycationic polymer and the pharmacologically active agent are ionically complexed, and therefore is a non-covalent association (col. 11 lines 65-67). Illum teaches a method of administering said composition to a mammal (col. 12 lines 43-58; claims 67-74). Illum teaches that the pharmacologically active agent can be selected from vasoconstrictors, vasodilators, enzymes, and hormones, which are proteins that do not have to include insulin, botulinum toxins, VEGF, or antibody fragments (col. 12 lines 4-10; claims 67-74).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-69, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-55, 64-73, 77-118, 146, 149-150 of copending Application No. 10591732 ('732). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '732 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '732 application would be considered a biologically active protein (recited in instant claim 67).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-69, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-80, 84, 90-94 of copending Application No. 10591485 ('485). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '485 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The biologically active protein which does not therapeutically



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alter blood glucose levels of the '485 application would be considered a biologically active protein (recited in instant claim 67).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-69, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 12647677 ('677). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '677 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '677 application would be considered a biologically active protein (recited in instant claim 67). Further, claim 10 of the '677 application recites that the treatment is for wrinkles, which one of ordinary skill would know could be considered a topical application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-44 of copending Application No. 11816666 ('666). Although the conflicting claims are not identical, they are not patentably

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distinct from each other because both the instant claims and the '666 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-69, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11 of copending Application No. 11816602 ('602). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '602 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '602 application would be considered a biologically active protein (recited in instant claim 67). While the composition of the '602 application can comprise at least one member selected from the group consisting of a partitioning agent, oligo-bridge, and polyanion bridge, it should be noted that the use of open claim language "comprising" in instant claim 67 does not preclude additional ingredients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha M. Tsay/  
Examiner, Art Unit 1656

April 26, 2010